

## REMARKS

### I. Introduction

Claims 1, 4, 5 and 7-15 are currently pending in this application. The withdrawal of all of the previous rejections is acknowledged.

Claims 1, 4, 5, 7, 8, 11, 12 and 15 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Smith U.S. 5,464,775. Claims 9, 10, 13, 14 have been indicated as allowable if written in independent form.

For the following reasons this application should be allowed and the case passed to issue.

### II. Claim Rejections under 35 U.S.C. § 103(a)

Claims 1, 4, 5, 7, 8, 11, 12 and 15 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Smith U.S. 5,464,775. Applicants respectfully disagree.

Claims 1 and 8 each recite in pertinent part, “a step of obtaining  $(dS1/dt)/S1$  (wherein  $S1$  is the measured value of the optical property obtained and  $T$  is the elapsed period of time since the start of the measurement after the mixing).” Claims 5 and 12 each recite in pertinent part, “a step of obtaining  $(dS1/dt)/(S1-S0)$  (wherein  $S0$  is the measured value of the optical property of said test liquid,  $S1$  is the measured value of the optical property of said liquid mixture, and  $T$  is the elapsed period of time since the start of the measurement after the mixing).”

The Examiner first concedes on pages 3 and 4, paragraph 6 of the June 20, 2008 Office Action that, “Smith does not specifically disclose a step of obtaining  $(dS1/dt)/S1$ ,” but then asserts, “but it would have been obvious to one having ordinary skill in the art at the time the invention was made to calculate the  $(dS1/dt)/S1$  value since during inspection, all of the variables, such as the absorbance measurements at 30 second intervals are recorded from the

automatic analyzers to determine the change in absorbance throughout the process of mixing the urine and reagent.”

Moreover, the Examiner also initially concedes on page 4, paragraph 8, that "Smith does not specifically disclose a step of obtaining  $(dS1/dt)/(S1-S0)$ ." Again, however, the Examiner asserts,

“but it would have been obvious to one having ordinary skill in the art at the time the invention was made [to] use the values that were obtained from the first absorbance reading and the continuous absorbance readings at 30 second intervals to calculate  $(dS1/dt)/(S1-S0)$  to determine in change in optical absorbance changes over the time the urine and reagent indicator were mixing taking into account the first absorbance reading to normalize the change within the 30 second interval time that is predetermined by the specification parameters of the analyzer.”

A similar assertion is made by the Examiner on pages 5-8, paragraphs 10 and 12.

However, in order to establish a *prima facie* obviousness rejection under 35 U.S.C. § 103(a), basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must not be based on applicant’s disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Further, “rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *In re Kahn*, 441 F. 3d 977, 988 (Fed. Cir. 2006).

At a minimum, the Examiner has not provided any basis for making the proposed modification absent the reference to the Applicants specification, which is not permissible.

Indeed, as acknowledged in the rejection, Smith neither discloses nor suggests determining  $(dS1/dt)/S1$  or  $(dS1/dt)/(S1-S0)$ , much less using these formulas to calculate predetermined values.

Moreover, Smith teaches “t” as an arbitrary 30 second time period, but does not recognize the use of “t” in determining whether the test liquid and the reagent liquid have been substantially homogenously mixed with each other as claimed.

Furthermore, the method using  $(dS1/dt)/S1$ , as recited in claims 1 and 8, yields better results than would have been expected by one having ordinary skill in the art. Specifically, as discussed on page 42, line 3-10 of the instant specification,

“[a]s described above, according to this embodiment, the concentration can be measured in a necessary and sufficient measurement time while the accuracy is ensured, so that the measurement time can be shortened. Further, it is possible to detect the degradation in accuracy due to relatively insufficient completion of the reaction which may occur when the test liquid is in a low concentration range, so that the reliability can be improved.”

In addition, the method using  $(dS1/dt)/(S1-S0)$  as an index as recited in claims 5 and 12, yields a highly reliable measurement, as well as a measurement without being effected by the turbidity of a test liquid prior to the injection of a reagent liquid, even when the concentration of the test liquid is low. This unexpectedly superior result is discussed on page 43, lines 17 to page 44, line 2 of the instant specification, wherein the claimed method, “can detect the degradation in accuracy due to relatively insufficient completion of the reaction which may occur in the case of a low-concentration-range test liquid, without being influenced by the turbidity of the test liquid itself, so that the reliability can be further improved.”

Therefore, it is respectfully submitted that it would not be obvious to one having ordinary skill in the art to derive the two formulas,  $(dS1/dt)/S1$  and  $(dS1/dt)/(S1-S0)$  from Smith, let alone predict the effect of these formulae.

Accordingly, claims 1, 5, 8 and 12 are allowable over the cited prior art references.

Furthermore, claims 4, 7, 9-11 and 13-15, depend from and further define the subject matter of base claims 1, 5, 8 and 12 respectively and therefore are also allowable.

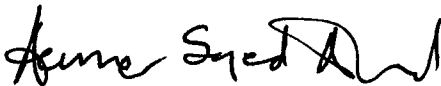
### **III. Conclusion**

In view of the above amendments and remarks, Applicants submit that this application should be allowed and the case passed to issue. If there are any questions regarding this Amendment or the application in general, a telephone call to the undersigned would be appreciated to expedite the prosecution of the application.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Respectfully submitted, .

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